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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,490	04/06/2001	Elizabeth S. Stuart	08952-008001 / UMA 00-19	5744

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/827,490	STUART ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Office Action is responsive to Applicant's response filed September 2, 2002. Claim 8 has been amended. Claims 1-6, 11-14 and 16 have been cancelled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

3. In view of Applicant's amendment and Response, the following Objections/Rejections have been withdrawn:

a) Objection to claim 7, page 2, paragraph 2, of the previous Office action.
b) Rejection of claims 7 and 9 under 35 U.S.C. 102(b), pages 2-3, paragraph 3 of the previous Office action.
c) Rejection of claims 7 and 9 under 35 U.S.C. 102(b), pages 3-4, paragraph 4 of the previous Office action.
d) Rejection of claims 7-10, 15 and 17 under 35 U.S.C. 103(a), pages 5-6, paragraph 6 of the previous Office action.

Rejection Maintained

4. The rejection of claim 15 under 35 U.S.C. 102(b) as being anticipated by Stuart et al is maintained for the reasons set forth on, page 4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Stuart et al teach purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining. The purified chlamydial glycolipid exoantigen of Stuart, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's exoantigen with the exoantigen of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the exoantigen of the prior art does not possess the same material structural and functional characteristics of the claimed exoantigen). See In re

Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Stuart et al do not disclose purified chlamydial glycolipid (GLXA) that is free of other components. Applicant urges that the preparations described in Stuart et al include GLXA and a mixture of other materials. Applicant urges that Stuart et al acknowledges that their preparations contain contaminants. Applicant urges that Stuart et al do not teach each and every element of claim 15 and therefore does not anticipate the claim.

Applicant's arguments filed September 24, 2001 in paper no. 9 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show why the chlamydial glycolipid of the reference is not the same as the claimed chlamydial glycolipid. Stuart et al teach purified GLXA isolated by molecular shift or affinity chromatography and Stuart et al teach that silver staining of SDS-PAGE gels demonstrate that pattern bands that is essentially the same for preparations isolated by either method (see the Abstract). Stuart et al teach that antigen purified was transferred to nylon membrane and visualized as a Western blot using GLXA antibodies to assure that purified GLXA was obtained (page 470) and the GLXA was further analyzed by isoelectric focusing techniques (471). It should be noted that Applicant's specification discloses that "purified chlamydial glycolipid exoantigen wherein the purified chlamydial glycolipid exoantigen that is free of other components as determined by sodium dodecylsulfate gel electrophoreses and silver staining was prepared according to the teachings of Stuart et al, (Immunology, 1989, 68, p. 469-473)"

(page 2). Applicant has provided no side-by-side comparison to show: that the chlamydial glycolipid exoantigen of the prior art is different from that of the claimed invention. There is nothing on the record to show that the purified chlamydial glycolipid exoantigen of the prior is different from the claimed purified chlamydial glycolipid exoantigen.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7-9 and 17 are rejected under 35 U.S.C. 102(b) as anticipated MacDonald et al *(U.S. Patent 5,716,793, published February 10, 1998).*

Claims 7-9 and 17 are drawn to a composition comprising a carrier protein coupled to oligosaccharide obtained from a chlamydial glycolipid.

MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40). The linker used to couple the carrier group to the oligosaccharide would be inherent in the teachings of the prior art. The composition of MacDonald, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7-10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al *(U.S. Patent 5,716,793, published February 10, 1998)* in view of Smith et al *(Journal of Biological Chemistry, 255(1), 1980, p. 55-59).*

Claims 7-10 and 17 are drawn to a composition comprising a carrier group coupled to an oligosaccharide obtained from a chlamydial glycolipid.

MacDonald et al teach purified chlamydial exoglycolipid antigen (GLXA) (column 8, lines 35-36). MacDonald et al teach a covalently bound immune complex comprising paramagnetic particles (i.e. carrier group), GLXA, GLXA-antibody and GLXA-antibody labeled monoclonal GLXA-antibody IgG) (column 14, lines 34-40).

MacDonald et al do not teach the use of linker 2-(4-aminophenyl)ethylamine linkers.

Smith et al teach the β-(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) can be used to couple proteins via their phenylisothiocyanate intermediates under conditions that preserve labile sugar linkages (see the Abstract). Smith et al teach the coupling of oligosaccharides to bovine serum albumin and keyhole limpet hemocyanin (see the Abstract). Smith et al teach that rabbits immunized with the synthetic glycoproteins produced antibodies directed against the oligosaccharides (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the β-(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) linkers as taught by Smith et al to covalently bond the carrier group (i.e. paramagnetic particles) to the oligosaccharide of MacDonald et al because Smith et al have demonstrated that β-(p-aminophenyl)ethylamide linkers can be used to form oligosaccharide-protein conjugates (see the Abstract). One would be motivated use of β-(p-aminophenyl)ethylamine linkers to produce the claimed chlamydial glycolipid-oligosaccharide conjugated of MacDonald because Smith et al teach the β-(p-aminophenyl)ethylamide (i.e. 2-(4-aminophenyl)ethylamine) can be used to couple proteins via their phenylisothiocyanate intermediates under conditions that preserve labile sugar linkages (see the Abstract).

Status of Claims

7. No claims are allowed.

Pertinent Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(Jeffery et al, Biochemical and Biophysical Research Communications, Vol. 62, No. 3, 1975).*

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
November 16, 2002

MARK NAVARRO
PRIMARY EXAMINER